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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,892	10/17/2003	Jose A. O'Daly	17595-3	1782

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PATENT DOCKET ADMINISTRATOR
LOWENSTEIN SANDLER PC
65 LIVINGSTON AVENUE
ROSELAND, NJ 07068

EXAMINER	
GRASER, JENNIFER E	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,892	O'DALY, JOSE A.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *12-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In response to the Restriction Requirement of 10/4/06, Applicant cancelled all claims (which were drawn solely to nucleic acids) and replaced them with claims 12-53 which are drawn to compositions comprising polypeptides and methods of eliciting an immune response in an animal for treatment of said symptoms of psoriasis. Accordingly, this amendment has necessitated the following new Restriction Requirement. It is noted that the new claims 12-32 appear to be drawn to an invention which was examined and patented in parent application 09/809,003 (US Patent Serial No. 6,673,351).

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:1, classified in class 530, subclass 350.

   II. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:2, classified in class 530, subclass 350.

   III. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof

wherein the at least one polypeptide is SEQ ID NO:3, classified in class 530, subclass 350.

IV. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:4, classified in class 530, subclass 350.

V. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:5, classified in class 530, subclass 350.

VI. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:6, classified in class 530, subclass 350.

VII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:7, classified in class 530, subclass 350.

VIII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:8, classified in class 530, subclass 350.

IX. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:9, classified in class 530, subclass 350.

X. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:10, classified in class 530, subclass 350.

XI. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:11, classified in class 530, subclass 350.

XII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:12, classified in class 530, subclass 350.

XIII. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof wherein the at least one polypeptide is SEQ ID NO:13, classified in class 530, subclass 350.

XIV. Claims 12-32, drawn to a composition for treatment of psoriasis comprising at least one immunogenic polypeptide and fragments thereof

wherein the at least one polypeptide is SEQ ID NO:14, classified in class 530, subclass 350.

XV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:1, classified in class 424, subclass 234.1.

XVI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:2, classified in class 424, subclass 234.1.

XVII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:3, classified in class 424, subclass 234.1.

XVIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:4, classified in class 424, subclass 234.1.

XIX. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:5, classified in class 424, subclass 234.1.

XX. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:6, classified in class 424, subclass 234.1.

XXI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:7, classified in class 424, subclass 234.1.

XXII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:8, classified in class 424, subclass 234.1.

XXIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis,

comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:9, classified in class 424, subclass 234.1.

XXIV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:10, classified in class 424, subclass 234.1.

XXV. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:11, classified in class 424, subclass 234.1.

XXVI. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:12, classified in class 424, subclass 234.1.

XXVII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and

fragment thereof wherein the at least one polypeptide is SEQ ID NO:13, classified in class 424, subclass 234.1.

XXVIII. Claims 33-53, drawn to a method for eliciting an immune response in an animal, including humans, for treatment of the symptoms of psoriasis, comprising introducing at least one immunogenic polypeptide and fragment thereof wherein the at least one polypeptide is SEQ ID NO:14, classified in class 424, subclass 234.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I-XIV and XV-XXVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptides of Groups I-XIV, may be used in materially different processes, e.g., they may be used as reagents in a diagnostic assay.

The compositions of Groups I-XIV comprise products which are biologically, chemically and structurally different. The proteins comprise different amino acid sequences and are from different species of leishmania. Accordingly, they are patentably distinct and independent inventions. Applicants must elect a single polypeptide composition for examination, e.g., a composition comprising SEQ ID NO:1; a composition comprising SEQ ID NO:1 and SEQ ID NO:14; a composition comprising SEQ ID NO:5, 8 and 13; etc.. All of the compositions would comprise completely

different products and possess completely different immunogenic properties. They would stimulate different immune responses and have different treatment capacities. Accordingly, they represent different inventions and are not merely species of one another. The methods of Groups XV-XXVIII use immunogens which are biologically, chemically and structurally different. The proteins to be administered comprise different amino acid sequences and are from different species of leishmania. Accordingly, the methods of using these different compositions are patentably distinct and independent inventions. Applicants must elect a single polypeptide composition for use in the method for examination, e.g., a method which uses a composition comprising SEQ ID NO:1; a method which uses a composition comprising SEQ ID NO:1 and SEQ ID NO:14; a method which uses a composition comprising SEQ ID NO:5, 8 and 13; etc.. All of these methods would comprise completely different products and possess completely different immunogenic properties. They would stimulate different immune responses and have different treatment capacities. Accordingly, they represent different inventions and are not merely species of one another.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and their recognized divergent subject matter and because the literature search required for the Groups is not coextensive, restriction for examination purposes as indicated is proper. It would place a serious undue burden on the Examiner to examine all of the Groups together.

3. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the

Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

Jennifer Graser
Primary Examiner
Art Unit 1645

12/20/06